

Office Action Summary

Application No.

09/630,319

Applicant(s)

KRIEG ET AL

Examiner

James Martinell

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 42-131 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1 and 42-131 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1633

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 50-57, 59-87, drawn to nucleic acids, classified in class 536, subclass 23.1.
- II. Claims 42, 43, and 46-49, drawn to methods of preventing and treating viral infections with a CpG oligonucleotide, classified in class 514, subclass 44.
- III. Claims 44 and 58, drawn to methods of treating viral infection with CpG oligonucleotides that do not include a palindrome of six nucleotides or longer, classified in class 514, subclass 44.
- IV. Claim 45, drawn to methods of treating viral infection with an oligonucleotide $GCGX_nGCG$ wherein X is a nucleotide and n is 0 to 50, classified in class 514, subclass 44.
- V. Claims 88-101, 103, and 104 drawn to methods of preventing bacterial infection using CpG oligonucleotides, classified in class 514, subclass 44.
- VI. Claims 102 and 105-110, drawn to methods of treating bacterial infection with CpG oligonucleotides that do not contain a palindrome of six nucleotides or longer, classified in class 514, subclass 44.
- VII. Claims 111-124 and 126-131, drawn to methods of treating fungal infections with CpG oligonucleotides, classified in class 514, subclass 44.
- VIII. Claim 125, drawn to methods of treating fungal infections with CpG oligonucleotides that do not include a palindrome of six nucleotides or longer classified in class 514, subclass 44.

The inventions are distinct, each from the other for the following reasons. The nucleic acids of Group I have uses other than in the methods of any of Groups II-VIII. For example, the oligonucleotides of Group I may be used in affinity chromatography. Each of the methods of Groups II-VIII can be used independently of one another. Groups II and III require the use of oligonucleotides with different structures. Groups V and VI require the use of oligonucleotides with different structures. Likewise, Groups VII and VIII require the use of oligonucleotides with different structures. The methods of preventing and/or treating viral infections (Groups II and III) are independent and distinct from the

Art Unit: 1633

methods of preventing and/or treating either bacterial infections (Groups V and VI) and are independent and distinct from the methods of preventing and/or treating fungal infections (Groups VII and VIII) because the methods of administration, oligonucleotide sequences that may or may not be effective in such treatments, and the dosages required may differ for each type of pathogen. The oligonucleotides used in the method of Group IV are independent and distinct from the oligonucleotides of each of Groups I-III and V-VIII; thus the methods of Group IV are independent and distinct from each of the methods of Groups I-III and V-VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each of the Groups is separate, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1633 at (703) 308-4242. The faxing of such papers must conform to the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this Office action should be directed to J. Martinell at telephone number (703) 308-0296. The fax phone number for Examiner Martinell's workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@USPTO.gov. Since e-mail may not be

Art Unit: 1633

secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah R. Clark, can be reached at (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JAMES MARTINELL, PH.D.
SENIOR LEVEL EXAMINER